Remote Diagnostic Technologies Ltd - Tempus Pro™ Patient Monitor 510k
Summary of Safety and Effectiveness

JUN 0 5 2013

510(k) Summary of Safety and Effectiveness

Submitter Information

Name:	Remote Diagnostic Technologies Ltd
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Contact Name:	Chris Hannan
Date Prepared:	January 2013

Device Name

Common Name:	Portable Patient Monitor
Proprietary Name:	Tempus Pro™ Patient Monitor
Classification Name:	Monitor, physiological, patient (without arrhythmia detection or alarms)

Device Description

The Tempus Pro is a multi-parameter vital signs monitor designed for use in pre-hospital care and remote clinical locations by trained healthcare professionals. It provides 3 & 5 Lead ECG monitoring and 12 Lead ECG recording, impedance pneumography, non-invasive blood pressure (NIBP), end-tidal CO2 (ETCO2) and respiration rate, pulse oximetry (SpO2), contact temperature and invasive pressure..

In addition, it provides the ability to transmit all vital signs data via wired Ethernet or wireless WiFi connections to a software system (called i2i) expected to be based in a facility far from the user e.g. a response centre facility. In addition to sending all vital signs, the system can also capture and transmit other data including still or moving pictures via an integrated camera, geographic position by an integrated GPS receiver and voice via a wired or wireless headset.

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It is expected that the ability to transmit data in real-time will be performed in remote locations typically using satellite or terrestrial communications systems.

The Tempus Pro is used in conjunction with I2I software, which provides a system for receiving real-time voice and medical data. The system enables users to receive voice, vital signs data and other medical data, still and moving video pictures from the Tempus Pro devices.

The i2i system can be used by commercial response centre service providers or by individuals or organisations wishing to provide their own internal service

I2i also supports a full patient records database.

Intended Use
The Tempus Pro Patient Monitor is intended to be used in remote or pre-hospital care situations by trained healthcare professionals e.g. nurse, EMT, paramedic, physician, military medic etc.

The device is intended to be used primarily as a standalone monitor for traditional monitoring applications. It is expected that its real-time telemedicine capabilities will be used in a minority of applications. When its telemedicine features are used it is intended that this will be for the purpose of obtaining support in the diagnosis and treatment decisions for the patient e.g. where the patient is in a remote country and the user's organisation needs to make an extraction or repatriation decision.

Indications for Use
The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for 3 & 5 Lead ECG monitoring and 12 Lead ECG recording, impedance pneumography, non-invasive blood pressure (NIBP), end-tidal CO2 (ETCO2) and respiration rate, pulse oximetry (SpO2), contact temperature and invasive pressure.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, paediatrics and neonates.

Contraindications
The Tempus Pro does not replace a physician's care. The device is not an apnoea monitor.

The Tempus Pro is not intended to be used in strong magnetic or electro-magnetic fields which are generated for medical purposes e.g. MRI.

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Predicate Devices
The Tempus Pro™ Patient Monitor is predicated on our existing model, the Tempus IC Professional Patient Monitor, which was the subject of a previous submission (K101264). Additional predicates include: the Welch Allyn Propaq 206 Encore Patient Monitor (K012451) to demonstrate substantial equivalence (SE) for the overall application and medical parameter modules.

The Tempus Pro Patient Monitor has the same intended use as the Tempus IC Professional Patient Monitor, with the following additions; the Tempus Pro Patient Monitor is also intended for monitoring neonates, and provides medical monitoring parameter functions for invasive pressure and impedance respiration.

Testing
The Tempus IC Professional uses currently available (OEM) technology found in many legally marketed devices.

Area	Testing Performed
Safety	The device has been tested to IEC60601-1.
Defibrillation and electrosurgical protection	The device has been tested for operation with a defibrillator and operation with an electro-surgical unit according to IEC60601-1 (and relevant particular standards).
Environmental	The device has been tested to a range of environmental (temperature, altitude, humidity, vibration, shock) tests according to RTCA DO-160, MIL810, EN1789, EN13718-1, EN60068.
Ingress Protection	The device has been tested to IEC60529 for solid and water ingress.
ECG monitoring	Testing to AAMI EC11 & EC13 and IEC60601-2-25 & IEC60601-1-27 has been performed.
EMC	The device has been tested to IEC60601-1-2 for emissions and immunity and RTCA DO-160 for radiated emissions.
Alarms	The alarm functions of the product have been tested to IEC60601-1-8.
Invasive pressure	The device has been tested to IEC60601-2-34.
Contact temperature	The device has been tested to EN12470-4 and IEC80601-2-56

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Area	Testing Performed
Comparative testing to predicates	Comparative testing has been performed to demonstrate that the performance of the device is equivalent to the predicates.
Software	The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of IEC62304 and IEC60601-1-4 have been addressed.
Bench testing	All parameters of the device have been tested to confirm they operate to specification across their stated performance range and across their stated temperature range.
Bench testing	The product has been bench tested to confirm that all data is transmitted reliably and accurately.
Wireless range	The device has been tested to confirm it operates reliably at its maximum stated range.
Wireless co-existence testing	The thermometer has been tested to confirm it operates reliably in the presence of other wireless fields as per the FDA Guidance for Radio-Frequency Wireless Technology in Medical Devices.

Evidence of Conformity to Essential Principles

The device has been shown to conform to the essential principles for safety and performance defined in guidance prepared by the Global Harmonization Task Force Study Group1 (GHTF/SG1/N14R9:2005), with supporting evidence prepared in the summary technical documentation (STED) format recommended in final version of GHTF guidance (SG1/N011: 2008).

Specifically, this evidence includes performance testing, software validation, electrical safety, electromagnetic compatibility etc..

The design of this device utilises currently available (OEM) technology found in many legally marketed devices. In terms of measurement performance, the Tempus Pro™ is effectively identical to the devices that incorporate the same OEM technology.

Conclusion

On the basis of these results and the above referenced testing, it is our determination that the device is safe, effective and performs as well as, or better than, the legally marketed predicate device(s).

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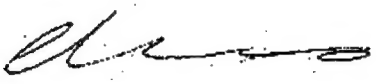
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully



Chris Hannan
Programme & Regulatory Affairs Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2013

Remote Diagnostic Technology Limited
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K130773
Trade/Device Name: Tempus Pro
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: May 20, 2013
Received: May 21, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

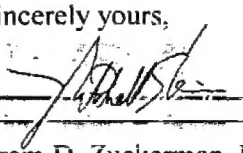
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): Not known

Device Name: Tempus Pro™ Patient Monitor

Indications for Use

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The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, paediatrics and neonates.

Prescription Use: YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2013.06.05 16:49:33 -04'00'

for Bram Zuckerman